UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

[UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No. COMPLAINT **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)**

DOCUMENT TO BE KEPT UNDER SEAL

Nola Hitchcock Cross
njhcross@crosslawfirm.com
CROSS LAW FIRM, S.C.
845 North 11th St.
Lawyers' Building
Milwaukee, Wisconsin 53233
Tel: (414) 224-0000
Fax: (414) 273-7055

Timothy P. McCormack
tmccormack@phillipsandcohen.com
Peter W. Chatfield
peter@phillipsandcohen.com
Molly B. Knobler
mknobler@phillipsandcohen.com
PHILLIPS & COHEN LLP
2000 Massachusetts Ave, NW
Washington, DC 20002
Tel: (202) 833-4567
Fax: (202) 833-1815

Attorneys for [under seal]

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, and the STATE OF WISCONSIN, ex rel. DR. CLARK SEARLE Plaintiffs, vs. AGNESIAN HEALTHCARE, INC., and FOND DU LAC REGIONAL CLINIC, S.C., Defendants.	Case No. COMPLAINT FOR VIOLATION OF THE FEDERAL and WISCONSIN FALSE CLAIMS ACTS **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED**

Plaintiff-Relator Dr. Clark Searle, through his attorneys, on behalf of the United States of America (the "Government," or the "Federal Government") and the State of Wisconsin ("the State" or the "Plaintiff-State"), for his Complaint against Defendants Agnesian HealthCare, Inc. and Fond du Lac Regional Clinic, S.C. (collectively "Defendants" or "Agnesian"), alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the State of Wisconsin arising from false and/or fraudulent records, statements, and claims made and caused to be made by Defendants and/or their agents and employees in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq*., and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 29.931.

2. This *qui tam* case is brought against Defendants for knowingly defrauding the federal Government and the state of Wisconsin, in connection with Medicare, Medicaid, and other government-funded healthcare programs. As alleged below, since 1996, Agnesian has

engaged in a scheme to pay improper compensation to physicians to induce them to illegally refer patients to its hospitals and associated medical facilities for medical services paid for by government-funded healthcare programs, including "designated health services" as defined by the Stark Law.

3. Agnesian, a three-hospital system in Wisconsin, controls approximately 60-70% of the healthcare market in the Fond du Lac region. This market dominance is largely driven by Agnesian's vast network of affiliated physicians, all of whom are pressured to, and almost exclusively do, refer internally to Agnesian physicians and facilities. Agnesian has put significant effort and resources into expanding its network of affiliated physicians so as to control their referral streams and maintain market dominance.

4. To acquire these affiliations, Agnesian knowingly and willfully made, and continues to make, illegal and improper payments to the physicians employed through its affiliated physician group to ensure that they refer all, or substantially all, of their patients to Agnesian rather than a competitor. Such payments, and Agnesian's subsequent submission of claims related to these illegally referred patients, violate the Anti-Kickback Statute, the Stark Law, and the False Claims Act.

5. As alleged in greater detail below, Agnesian's illegal physician payments are comprised of several elements. First, when calculating each physician's cash compensation, Agnesian factors in a "Department Adjustor" or "DA," designed to reflect the value of that physician's specialty's referrals to Agnesian hospitals, facilities, services, and other Agnesian physicians. Second, when calculating physician compensation, Agnesian over-values physician services and regularly credits physicians with a portion of the fees earned by Agnesian facilities for services performed by Agnesian. A third key component of Agnesian's overcompensation is

the use of "deferred compensation" payments tied to an expansive agreement limiting the physician's ability to refer patients to Agnesian's competitors should he or she leave Agnesian. Finally, Agnesian also routinely cuts side-deals, giving high-referring physicians additional compensation or other valuable consideration above and beyond the basic compensation model.

6. Taken together, Agnesian's payments to many of its physicians are above fair market value and commercially unreasonable (absent consideration of those physicians' referrals). These overpayments are made to ensure that the physicians refer all, or substantially all, of their patients to Agnesian hospitals, facilities, services, and physicians.

7. Federal law, specifically the Stark Law (42 U.S.C. § 1395nn) and Anti-Kickback Statute (42 U.S.C. § 1320a-7b), prohibit hospitals and other medical providers from paying physicians in exchange for referring them business paid for by government-funded healthcare programs. Moreover, all claims submitted to Medicare, Medicaid, or other government-funded healthcare programs, for services provided pursuant to referrals from physicians with whom the billing provider has improper financial relationships, are false within the meaning of the federal False Claims Act.

8. Through the acts described above, and in greater detail below, Defendants have submitted and caused to be submitted tens of thousands of fraudulent claims to federal and state-funded healthcare programs for services provided pursuant to kickback-tainted referrals and/or based on referrals from physicians with whom Defendants had financial relationships not falling within a Stark safe harbor. Each submission is a false or fraudulent claim in violation of the federal and Wisconsin False Claims Acts.

9. The federal False Claims Act (the "FCA") was originally enacted during the Civil War. Congress substantially amended the Act in 1986 – and, again, in 2009 and 2010 – to

enhance the ability of the United States Government to recover losses sustained as a result of fraud against it. The Act was amended after Congress found that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

10. The FCA prohibits, *inter alia*: (a) knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval; (b) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; (c) conspiring to knowingly present or cause to be presented to the federal government a false or fraudulent claim for payment or approval; and (d) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government. 31 U.S.C. §§3729(a)(1)(A)-(C), and (G). Any person who violates the FCA is liable for a civil penalty of up to $11,000 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. §3729(a)(1).

11. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

12. The Wisconsin False Claims for Medical Assistance Law prohibits similar conduct as that prohibited by the Federal FCA, allows plaintiffs to bring an action on the State's behalf, and provides analogous remedies to those provided in the Federal FCA. As set forth below, Defendants' actions alleged in this Complaint also constitute violations of the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 29.931.

13. Based on the foregoing laws, *qui tam* plaintiff Dr. Clark Searle seeks, through this action, to recover damages and civil penalties arising from the false or fraudulent records, statements and/or claims that the Defendants made or caused to be made by seeking payment from government-funded healthcare programs for services performed pursuant to referrals from physicians who were financially incentivized to align themselves with Defendants and refer internally for Defendants' benefit.

II. PARTIES

14. Plaintiff-Relator Dr. Clark Searle is an orthopedic surgeon and resident of Fond du Lac, Wisconsin. Dr. Searle was recruited to practice at Defendant Fond du Lac Regional Clinic in 2006. In 2008, Dr. Searle was made a "shareholder" of the Fond du Lac Regional Clinic. Dr. Searle has served in several Clinic leadership roles. From 2010 through 2013, he was on the Clinic Board of Directors. Between 2008 and 2011, and from 2013 until the present, he has been a member of the Clinic Professional Services Agreement ("PSA") Committee. And in 2013 he served on the Clinic Compensation Committee.

15. Dr. Searle has repeatedly raised concerns about and attempted to reform the improper compensation arrangements detailed below. For example, at a March 5, 2014 meeting of the Clinic's PSA Committee, attended by among others, Dr. Derek Colmenares, Chief Medical Officer of Agnesian HealthCare, and Dr. Mary Schultz, the immediate past Clinic

President, Dr. Searle stated explicitly that "The [Department Adjustment Factor] is illegal and is a clear Stark violation." On March 17, 2014, at an FDLRC Shareholder meeting, Dr. Searle again stated his belief that the physician compensation plan violated relevant regulations. As of the filing of this complaint, Dr. Searle's complaints and warnings have been ignored.

16. Defendant Agnesian HealthCare ("AHC") is a non-profit, three-hospital health system based in Fond du Lac, Wisconsin. Its principal office is located at 430 E. Division St., Fond du Lac, Wisconsin. The largest hospital, St. Agnes, is located in Fond du Lac and has approximately 100 inpatient beds. St. Agnes' patient mix is made up of approximately 40% Medicare and Medicaid patients. AHC's two other hospitals are located in Ripon and Waupun, Wisconsin. AHC also includes over a dozen clinics staffed by the physicians employed by Defendant Fond du Lac Regional Clinic.

17. Although AHC is a non-profit entity, and therefore does not technically realize profits, its year end "revenues minus expenses" is the functional equivalent of profit. These "profits" have risen significantly over the last few years, going from $7.62 million in 2009 to $24.2 million in 2012.

18. Defendant Fond du Lac Regional Clinic, S.C. (the "Clinic" or "FDLRC") is a for-profit Wisconsin service corporation. Its principal office is located at 420 E. Division St., Fond du Lac, Wisconsin. It is a multi-specialty physician group of about 100 physicians. Since 1996, it has had a PSA with Agnesian HealthCare under which it provides physician services exclusively for Agnesian. In exchange, Agnesian pays all of the Clinic's expenses including physician salaries as well as all overhead costs.

19. The operations and management of AHC and the Clinic are closely intertwined. First, FDLRC and AHC have overlapping leadership. Under the PSA, three Clinic physician-

employees sit on the Agnesian Board of Directors. Currently, Dr. Michael Strigenz, the Chairman of the Clinic PSA Committee, sits on the AHC Board of Directors. Dr. Robert Mikkelsen, the current Clinic Vice-President, has previously served on the AHC Board of Directors. AHC's CEO and CFO attend all Clinic Board of Directors meetings. All significant decisions by the Clinic Board or Committees, such as decisions to raise physician compensation, provide compensation guarantees, or hire or fire physicians, are cleared first with AHC's CEO, Steve Little.

20. In addition, almost all Clinic administrative functions are performed by AHC employees. For example, the Clinic's billing is performed by Agnesian employees, and the Clinic's Administrator is an employee of AHC. In fact, the Clinic has only a single non-physician employee, its accountant, Kate Cole, and even her salary is paid by AHC.

III. JURISDICTION AND VENUE

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) vests this Court with jurisdiction over the state law claims asserted in this Complaint.

22. Under 31 U.S.C. § 3730(e), and the analogous provisions of Wisconsin's False Claims Act, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Even if there had been any such public disclosure, Relator is the original source of the allegations herein because he has direct, independent and material knowledge of the information that forms the basis of this complaint, and voluntarily disclosed that information to the Government and the State before filing.

23. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in and have transacted business in the Eastern District of Wisconsin.

24. Venue is proper in the Eastern District of Wisconsin pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Defendants can be found in and transact or have transacted business in this district. At all times relevant to this Complaint, Defendants regularly conducted, and continue to conduct, substantial business within this district and/or maintain employees and offices in this district.

IV. APPLICABLE LAW

A. Federal and State-Funded Health Care Programs

1. The Medicare Program

25. Medicare is a federally-funded health insurance program which provides for certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

26. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. *See* 42 U.S.C. §§ 1395k, 1395l, 1395x(s). Medicare Part C covers certain managed

care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

27. To administer the Medicare program, private insurance companies act as agents of the Department of Health and Human Services, making payments on behalf of the program beneficiaries and providing other administrative services. 42 U.S.C. §§ 1395h and 1395u. These companies are called "carriers." 42 C.F.R. §§421.5(c). Through local carriers, Medicare establishes and publishes the criteria for determining what services are eligible for reimbursement or coverage. This information is made available to the providers who seek reimbursement from Medicare.

a. Medicare Contracts and Claims Submission

28. Medicare reimburses health care providers for the costs of providing covered health services to Medicare beneficiaries. *See* 42 U.S.C. § 1395x(v)(1)(A). In order to bill Medicare Part A, a provider must submit an electronic or hard-copy claim form called the UB-04 (also known as the CMS 1450) to the appropriate Medicare carrier. To bill Medicare Part B, a provider must submit an electronic or hard-copy claim form called the CMS 1500 (formerly known as HCFA 1500) to the appropriate Medicare carrier. These forms describe, among other things, the provider, the patient, the referring physician, the service(s) provided by procedure code, the related diagnosis code(s), the dates of service, and the amount charged. The provider certifies on the CMS 1500 claim form that the information provided is truthful and that the services billed on the form were "medically indicated and necessary." The provider certifies in the UB-04 that "[s]ubmission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate, and complete."

29. In addition, each Medicare provider must sign a provider agreement, and by so doing must agree to comply with all Medicare requirements including the fraud and abuse provisions. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medicare patients.

30. At all times relevant to this action, the local carriers that reviewed and approved the claims at issue in this case based their review upon the enrollment information and claim information provided by the Defendants, and relied on the veracity of that information in determining whether to pay the claims submitted by Defendants.

31. As a prerequisite to payment, Medicare also requires hospitals to submit annually a Form CMS-2552 (previously form HCFA-2552), more commonly known as the Hospital Cost Report. Cost reports are the final claim that a provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries.

32. Every Hospital Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator. Through this certification, the provider confirms that the cost report is "true, correct and complete" and that the services identified in the cost report "were provided in compliance with [the laws and regulations regarding the provision of the health care services]." The certification also states, *inter alia*: "if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result."

b. Medicare Payments for Hospital and Physician Services

33. Medicare pays hospitals for providing inpatient and outpatient care. Since 1983, Medicare, Medicaid, and other federally-funded health insurance programs have reimbursed

hospitals for inpatient care through a prospective payment system based on classification of patients through Diagnosis Related Groups (DRGs). DRGs are groups of clinically similar diagnoses and/or procedure codes, which are presumed to have similar resource utilization. Medicare pays a fixed amount per case by DRG.

34. Payments for outpatient hospital services are also based on bundled, per-case payment system. Hospitals use Ambulatory Payment Classification ("APC") codes to bill for costs associated with outpatient services. Similar to the DRG-based payment system for inpatient services, Medicare reimburses hospitals for outpatient services through standardized payments determined by the APC to which the claim is assigned.

35. Each claim is assigned one or more APCs based on the procedure codes (*i.e.*, HCPCS code, as described below) included on the claim form. Unlike inpatient DRG payments, where the hospital generally receives only one DRG payment per case, hospitals can receive multiple APC payments for the same outpatient case, depending on the nature of the services provided.

36. Physician services provided to either inpatients or outpatients are billed and reimbursed separately from the hospital's DRG or APC-based payment. Physician services are reimbursed through a payment system based on the Healthcare Common Procedure Coding System ("HCPCS"). HCPCS is a standardized coding system that groups procedures based on the level of professional effort required to render the service. Medicare pays physicians a fixed "global" amount for their services when they are performed in a physician's office. This payment includes both a "professional" component to compensate for the physician's services and a "technical" component to compensate for the cost of office space, supplies, etc.

37. When a physician performs services in a hospital setting (either inpatient or outpatient), Medicare pays the physician a "professional" fee, but does not pay the physician the "technical" component. Instead, the hospital is reimbursed for these costs through the DRG or APC payment.

38. This dichotomy between the professional and technical components of the Medicare payment gets somewhat more complicated, however, in situations where the physicians are in what are known as "provider-based" physicians' offices. Medicare allows certain physician practices to be considered part of the hospital facility, even when they are not physically located in a traditional hospital facility. If a provider practice qualifies as "provider based," the physicians bill for their professional services the same way they would bill for services performed in a hospital outpatient department, and then the hospital may bill the "technical" component of the service using the APC system. *See* 42 CFR § 413.65. As a general matter, Medicare pays hospitals substantially more for the "technical" component of provider-based physician services than it pays to independent physicians if they provide the same services in an office setting.

2. The Medicaid Program

39. Medicaid is a public assistance program providing for payment of medical expenses for low-income and disabled patients. Funding for Medicaid is shared between the Federal Government and those states participating in the program.

40. Federal regulations require each state to designate a single state agency responsible for the Medicaid program. The agency must create and implement a "plan for medical assistance" that is consistent with Title XIX and with the regulations of the Secretary of HHS ("the Secretary"). Although Medicaid is administered on a state-by-state basis, the state

programs adhere to federal guidelines. Federal statutes and regulations restrict the items and services for which the federal government will pay through its funding of state Medicaid programs.

41. Each provider that participates in the Wisconsin Medical Assistance program must sign a provider agreement with the State. Wis. Admin. Code DHS § 105.01(3)(e). In addition, Wisconsin regulations provide that a physician can only be reimbursed for services that are "appropriate and medically necessary," Wis. Admin. Code DHS § 106.02(5), and only when they are provided in compliance with "applicable federal and state procedural requirements." Wis. Admin. Code DHS § 106.02(4).

3. Other Federal and State-Funded Health Care Programs

42. The Federal Government administers other health care programs including, but not limited to, TRICARE/CHAMPUS, CHAMPVA, and federal workers' compensation programs.

43. TRICARE/CHAMPUS, administered by the United States Department of Defense is a health care program for individuals and dependents affiliated with the armed forces. 10 U.S.C. §§ 1071 *et seq*.; 32 C.F.R. § 199.4(a).

44. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. 38 U.S.C. §§ 1781 *et seq*.; 38 C.F.R. § 17.270(a).

45. The Federal Employees' Compensation Act provides workers' compensation coverage, including coverage of medical care received as a result of a workplace injury, to federal and postal employees. The Act is administered by the Department of Labor, Division of Federal Employees' Compensation. 5 U.S.C. §§ 8101 *et seq*.; 20 C.F.R. §§ 10.0 *et seq*.

46. Wisconsin provides health care benefits to certain individuals, based either on the person's financial need, employment status, or other factors. To the extent those programs are covered by Wisconsin's False Claims Act, those programs are referred to in this Complaint as "state-funded health care programs."

B. The Stark Law

47. A section of the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Law"), prohibits a hospital (or other entity providing healthcare items or services) from submitting claims to Medicare or Medicaid for payment based on patient referrals from physicians who have an improper "financial relationship" (as defined in the statute) with the hospital. *See* 42 U.S.C. § 1396b(s).

48. The Stark Law establishes that providers may not submit claims for items or services referred by physicians with whom the providers have financial relationships, unless the relationship falls within the confines of defined safe harbors.

49. In enacting the statute, Congress found that improper financial relationships between physicians and entities to which they refer patients can compromise the physician's professional judgment as to whether an item or service is medically necessary, safe, effective, and of good quality. Congress relied on various academic studies consistently showing that physicians who had financial relationships with medical service providers used more of those providers' services than similarly situated physicians who did not have such relationships. The statute was designed specifically to reduce the loss suffered by the Medicare program due to such increased questionable utilization of services.

50. Congress enacted the Stark Law in two parts, commonly known as Stark I and Stark II. Enacted in 1989, Stark I applied to referrals of Medicare patients for clinical laboratory

services made on or after January 1, 1992 by physicians with a prohibited financial relationship with the clinical lab provider. *See* Omnibus Budget Reconciliation Act of 1989, Pub. Law 101-239, § 6204.

51. In 1993, Congress amended the Stark Law (Stark II) to cover referrals for additional designated health services. *See* Omnibus Budget Reconciliation Act of 1993, Pub. Law 103-66, § 13562, Social Security Act Amendments of 1994, Pub. Law 103-432, § 152. Currently, the Stark Law applies to patient referrals by physicians with a prohibited financial relationship for the following twelve "designated health services" (DHS); (1) inpatient and outpatient hospital services; (2) physical therapy; (3) occupational therapy; (4) radiology; (5) radiation therapy (services and supplies); (6) durable medical equipment and supplies; (7) parenteral and enteral nutrients, equipment and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) outpatient prescription drugs; (10) home health services, (11) clinical laboratory services, and (12) outpatient speech-language pathology services. *See* 42 U.S.C. § 1395nn(h)(6).

52. In pertinent part, the Stark Statute provides:

> "(a) Prohibition of certain referrals
>
> (1) In general. Except as provided in subsection (b), if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then – (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made [by Medicare or Medicaid]; and (B) the entity may not present or cause to be presented a claim under this title or bill to any individual,

third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under (A)."

42 U.S.C. § 1395nn(a)(1) (emphasis added).

53. Therefore, a physician is prohibited from making referrals to an entity with which he or she has a financial relationship for DHS payable by Medicare or Medicaid. In addition, providers may not bill Medicare or Medicaid for DHS furnished as a result of a prohibited referral.

54. Further, no payment may be made by the Medicare or Medicaid programs for DHS provided in violation of 42 U.S.C. § 1395nn(a)(1). *See* 42 U.S.C. §§ 1395nn(g)(1); 1396b(s).

55. Finally, if a person collects payments billed in violation of 42 U.S.C. § 1395nn(a)(1), that person must refund those payments on a "timely basis," defined by regulation not to exceed 60 days. *See* 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d); 42 C.F.R. § 1003.101.

56. The Stark Statute broadly defines prohibited financial relationships to include any "direct or indirect compensation arrangement . . . with an entity that furnishes DHS." 42 C.F.R. § 411.354(a)(1). An entity is defined to "furnish" DHS if it performs or bills for the service. 42 C.F.R. § 411.351. The statute's exceptions then identify specific transactions that will not trigger its referral and billing prohibitions.

57. A "direct financial arrangement" exists when remuneration passes between the referring physician and the entity furnishing the DHS "without any intervening persons or entities." 42 C.F.R. § 411.354(a)(2). There are several safe harbors for direct financial arrangements, but the requirements of such must be met precisely.

58. For example, compensation paid pursuant to a bona fide employment relationship may be considered proper under the Stark Law, but only if: (1) the employment is for identifiable services; (2) the amount of remuneration under the employment (i) is consistent with the fair market value of the services and (ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and (3) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer. 42 C.F.R. § 411.357(c).

59. Similarly, compensation paid pursuant to a personal services arrangement between a hospital and a physician may be considered proper under the Stark Law, but only if: (1) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement; (2) the arrangement covers all of the services to be provided by the physician to the entity; (3) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the entity of the arrangement; (4) the term of the arrangement is for at least 1 year; (5) the compensation to be paid over the term of the arrangement is to be set in advance, does not exceed the fair market value for the services, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties (unless the agreement falls within the narrowly defined physician incentive plan); and (6) the services do not involve promoting any activity that violates state or Federal law. 42 C.F.R. § 411.357(d).

60. Physicians employed by hospitals either as employees or through personal service arrangements may be paid "productivity bonuses," but only if and to the extent that those bonuses are based solely on the value of services personally performed by the physician. 42 C.F.R. § 411.357(c)(4).

61. Finally, there is a catch-all safe harbor allowing entities to compensate physicians with whom they have an arrangement for the provision of items or services, so long as several provisions are met, including that the arrangement is commercially reasonable and the compensation is set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of the physician's referrals. 42 C.F.R. § 411.357(l).

62. An indirect compensation arrangement exists when: 1) an unbroken chain of persons or entities with financial relationships between them links the referring physician to the entity furnishing DHS; 2) the referring physician receives aggregate compensation from the entity with which the physician has a direct financial relationship that varies with, or otherwise takes into account, the volume or value of referrals or other business generated by the physician for the entity furnishing the DHS; and 3) the entity furnishing the DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives compensation that so varies. 42 C.F.R. § 411.354(c)(2).

63. To qualify for the Stark Statute's exception for indirect compensation arrangements, several elements must be established, including that the compensation received is fair market value for the services actually provided and is not determined "in any manner that takes into account the volume or value of referrals or other business generated" by the referring physician. 42 C.F.R. § 411.357(p).

64. Fixed aggregate compensation "takes into account" the volume or value of referrals or other business generated by a referring physician when the payment rate is set based on historical or expected referrals. *See United States ex rel. Drakeford v. Tuomey Healthcare Sys.*, 675 F.3d 394, 408 (4th Cir. 2012); *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*,

752 F. Supp. 2d 602, 631 (W.D. Pa. 2010); 69 Fed. Reg. 16054, 16059 (Mar. 26, 2004) ("It is important to bear in mind that, depending on the circumstances, fixed aggregate compensation can form the basis for a prohibited direct or indirect compensation arrangement. This will be the case if such fixed aggregate compensation takes into account the volume or value of referrals (for example, the fixed compensation exceeds fair market value for the items or services provided or is inflated to reflect the volume or value of a physician's referrals or other business generated).")

65. There are also special compensation provisions for physician members of "group practices" as defined by the Stark Law. 42 C.F.R. § 411.352. Physicians in group practices can be compensated through profit shares and productivity bonuses so long as these payments are not calculated in any manner directly related to the volume or value of the physician's referral of DHS. 42 C.F.R. § 411.352(i). The requirements for a group to qualify as a "group practice" are extensive and must be met precisely for these compensation methodologies to be available.

66. Stark-qualified "group practices" may also take advantage of a special provision that exempts from Stark referrals for services that qualify as "in-office ancillary services" (IOAS). Like the group practice rules, the IOAS exception is strictly limited to those services that meet the exception's specific billing, location, and performance requirements. 42 C.F.R. § 411.355(b).

67. The "group practice" rules do not protect referrals to a hospital or other non-group entity. If a hospital pays physicians who are members of a group (either directly, or indirectly by way of payments to the group that are then funneled to the individual physicians) any amounts that vary or take into account the volume or value of the referrals from the physician to the hospital, then the Stark Law is implicated. 66 Fed. Reg. 856, 869 (Jan. 4, 2001) ("Phase I of this

rulemaking would require that the compensation to the physicians not vary with or otherwise reflect either referrals to the group (to comply with the employee exception) or referrals to, or other business generated for, the hospital (so that it does not qualify as an indirect compensation relationship).")

68. Violations of the Stark Law may subject the physician and the billing entity to exclusion from participation in federal health care programs and various financial penalties, including: (a) a civil money penalty of up to $15,000 for each service included in a claim for which the entity knew or should have known that the payment should not be made; and (b) an assessment of three times the amount claimed for a service rendered pursuant to a referral the entity knows or should have known was prohibited. *See* 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

C. The Federal Anti-Kickback Statute

69. The Medicare and Medicaid Fraud and Abuse Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), was enacted under the Social Security Act in 1977. The Anti-Kickback Statute arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically inappropriate, unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

70. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care

program. 42 U.S.C. § 1320a-7b(b). The statute ascribes liability to both sides of an impermissible kickback relationship.

71. Claims for reimbursement for services that result from kickbacks are false under the False Claims Act. 42 U.S.C. § 1320a-7b(g)

72. The Anti-Kickback Statute contains statutory exceptions that exempt certain transactions from its prohibitions, such as contracts for employment or personal services.

73. The personal services safe harbor applies to payments to an agent as long as: (1) the agency agreement is in writing and signed by the parties; (2) the agreement specifies all of the services that the agent is to provide for the principal; (3) if "the agency agreement is intended to provide the services of the agent on a periodic, sporadic, or part-time basis" then the agreement must specify the intervals and their schedules and charges with specificity; (4) the term of the agreement must be not less than 1 year; (5) the aggregate compensation to the agent must be set in advance, "consistent with fair-market value," and not be determined "in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties;" (6) the services must not involve promotion of any activity that violates state or Federal law; and (7) the aggregate services contracted for must not exceed those reasonably necessary to accomplish the business purpose of the entity. 42 C.F.R. § 1001.952(d).

74. The employment safe harbor applies to all remuneration paid by an employer to a bona fide employee "for employment in the furnishing of any item or service for which payment may be made in whole or in part under" any Federal health care program. 42 C.F.R. §1001.952(i). This safe harbor provides a defense against Anti-Kickback Statute liability only where a bona fide employee is compensated exclusively for the provision of professional services that are covered by a federal health care program. Any payments to a bona fide

employee that are not, in fact, made for the provision of covered professional services do not fall within the safe harbor.

75. The act of referring a patient to a hospital or other provider is not a covered item or service. Therefore, any payments made to an employee in order to compensate that employee for making referrals are not covered by the employee safe harbor. This is true even if the majority of an employee's compensation is for the provision of covered services. As to that portion of the payments that is made to induce referrals and to compensate for an employee's act of referring, the Anti-Kickback Statute is violated and the safe harbor does not apply.

76. Once the Government has demonstrated each element of a violation of the Anti-Kickback Statute, the burden shifts to the defendant to establish that defendant's conduct at issue was protected by a safe harbor or exception. The Government need not prove as part of its affirmative case that defendant's conduct at issue does not fit within a safe harbor.

77. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. § 1320a-7(b)(7), 1320a-7a(a)(7).

78. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under the Medicare and Medicaid programs.

79. Either pursuant to provider agreements, claim forms, or other appropriate manner, hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback Statute.

80. Any party convicted under the Anti-Kickback Statute must be excluded (*i.e.*, not allowed to bill for services rendered) from federal health care programs for a term of at least five

years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agencies to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

81. The enactment of these various provisions and amendments demonstrates Congress' commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Stark and Anti-Kickback Statutes is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare, Medicaid and other federal health care programs.

V. BACKGROUND

A. The Fond du Lac Regional Healthcare Market

82. Between its three hospitals, 14-plus clinics, reference laboratories, and nursing home, Agnesian controls approximately 60-70% of the healthcare market in the Fond du Lac region.

83. Control of the referral streams of the Fond du Lac physicians is crucial to Agnesian because it faces stiff competition from Aurora HealthCare ("Aurora"). Aurora is a significantly larger healthcare network that dominates the southeastern corner of Wisconsin. It has a hospital, surgery center, and several physician offices about 20 miles from Fond du Lac in Oshkosh, Wisconsin. It also has physician office space and a surgery center in Fond du Lac. Over 30 Aurora-employed physicians, nurse practitioners, and physician assistants practice at least part-time at Aurora's Fond du Lac facilities.

84. On several occasions, physicians who had previously referred patients to Agnesian stopped doing so after they affiliated with Aurora. For example, until about 2 years ago, the Aurora-employed internists in Fond du Lac maintained privileges at St. Agnes and thus admitted patients and provided services there. Around 2012, Aurora informed these physicians that they could not maintain privileges at St. Agnes, effectively halting the flow of referrals from these physicians to Agnesian.

85. Similarly, around the beginning of 2014, Aurora hired two general surgeons who had previously had independent practices in Fond du Lac. Previously, these two physicians held privileges, took call, and frequently performed procedures at St. Agnes. Once Aurora hired them, they gave up their privileges at St. Agnes and stopped performing procedures at, or otherwise referring patients to, Agnesian facilities.

B. Relationship Between AHC and FDLRC

86. Defendant Fond du Lac Regional Clinic, a multi-specialty group of approximately 100 physicians, has affiliated exclusively with AHC since 1996. Under the PSA governing their affiliation, the Clinic furnishes the vast majority of physician services required by AHC patients at AHC clinic locations. The Clinic may not contract to provide physician services for any other entity.

87. AHC bills and collects for all of the Clinic's services. In exchange, AHC agrees to provide at its "sole cost and expense," "all necessary facilities, services and funding" for the performance of these physician services at AHC facilities, including, but not limited to, office space, furniture, equipment, personnel, and supplies, office administrative services, and management information services.

88. Thus, functionally, all Clinic technical fees are actually billed by Agnesian on its own behalf because AHC retains any profit and bears the risk of any loss arising from these services.

89. The Clinic has direct employment arrangements with the individual physicians. Physicians often come on as "associates" and then become "shareholders." Notably though, "shareholders" are owners of the Clinic in name only (*i.e.*, they are not entitled to profit shares, only their salaries and benefits).

90. The clinic-employed physicians are strongly encouraged to maintain privileges at Agnesian's hospitals and may not obtain privileges at Aurora's facilities.

91. Further, employed physicians are directed to use their "best efforts" to utilize Agnesian facilities and to refer patients to other Agnesian-affiliated physicians. They may refer outside of Agnesian only if the patient requests another facility or physician, the patient's insurance determines the facility or physician the patient will utilize, or in the referring physician's best medical judgment a referral to a non-Agnesian facility is in the patient's best interest. Agnesian tracks "leakage" of referrals outside of the system.

92. Agnesian keeps approximately 94% of the referrals of its affiliated physicians.

93. AHC pays annual aggregate compensation to the Clinic to cover the salaries of the Clinic's employed physicians. This includes payment for cash compensation as well as generous benefit packages.

94. As described in further detail below, physician cash compensation is calculated in part based on a "Department Adjustment Factor" or "DA" that varies by specialty. Because AHC is responsible for all physician compensation, any adjustments to physician compensation, including increases in a specialty's DA, are borne by AHC unless offset by decreased Clinic

costs elsewhere. For this reason, the Agnesian Physician Compensation Committee and Agnesian Board of Directors must approve any modifications to the DA.

95. The benefits paid to or on behalf of each physician include annually: $6,000 for continuing medical education, approximately $27,250 for health insurance, $1,000 for disability insurance, $1,705 for licenses and medical society dues, $460 for life insurance, at least $3,500 for malpractice insurance, $1,457 for contribution to the Wisconsin State Injured Patient and Families Compensation Fund, and substantial sums to fund the deferred compensation plan described further below.

VI. ALLEGATIONS

96. Agnesian pays the FDLRC physicians using a compensation methodology designed to reward them for their referrals to Agnesian facilities and physicians. The payment methodology does this in several ways.

97. First, the physicians' cash compensation is calculated using a "Department Adjustment" factor that rewards historically high-referring physicians.

98. Second, Agnesian improperly credits physicians with a portion of the fees earned by its facilities for the provision of services such as maintaining office space, nursing staff, and diagnostic equipment.

99. Third, Agnesian pays the physicians substantial "deferred compensation" that is tied to the physicians' agreements to continue to work for (and refer patients to) Agnesian, and to refrain from referring patients to Agnesian's competitors should the physicians leave Agnesian.

100. Finally, Agnesian makes special deals with certain high-referring physicians, offering them additional remuneration above what is available through the standard compensation model.

101. Taken together, the amounts Agnesian pays the FDLRC physicians are commercially unreasonable and above fair market value for the services provided (excluding the value of the physicians' referrals). All claims submitted by FDLRC or Agnesian for services referred by FDLRC physicians who receive commercially unreasonable, above fair market value compensation, and/or compensation based on the volume and value of their referrals, are false claims within the meaning of the Federal and Wisconsin False Claims Acts.

A. Agnesian Uses the "Department Adjustment Factor" to Compensate Physicians Based on the Volume and Value of Their Referrals to Agnesian Facilities and Doctors

102. The base salary for FDLRC physicians is calculated as follows: (1) the physician's "net monthly production;" (2) is multiplied by .49; and (3) multiplied by the physician's "Department Adjustment Factor;" and (4) then 30% of billed charges for charity care and bad debt cases handled by the physician is added.

103. The PSA provides that the "Department Adjustment Factor" or "DA" is to be set to "properly reflect market compensation by medical specialties consistent with the services provided in communities comparable to Fond du Lac County."

104. In reality, though, the DA is designed to adjust physician compensation to reflect the value of their historic referrals of ancillary services to the Clinic. When the AHC/FDLRC partnership was formed in 1996, the parties discussed the fact that the physicians could not be paid for their referrals because of the Stark Law. Rather than comply with this directive, to do exactly what the Stark Law (and Anti-Kickback Statute) prohibit, while appearing not to, they devised a way to ensure physicians continued to be compensated for their referrals. Prior to the partnership, the profits the Clinic realized on ancillary services were distributed among the physicians according to how much of the services each physician had ordered. To ensure that

physicians "were made whole" when the AHC/FDLRC partnership was formed, each physician was paid a set amount above and beyond his/her base compensation equal to the profits on his/her historical referrals for ancillary services. Over several years, these "bonus" payments became standardized across specialties and became the "DA."

105. Relator learned this from the Clinic's accountant, Kate Cole, and the Clinic's former administrator, Dennis Yunk, both of whom worked at the Clinic and were involved in the process of setting up the DA.

106. Moreover, at a March 13, 2014 meeting of the PSA Committee, Agnesian's Medical Director, Dr. Derek Colmenares, stated that "The DA was originally based on internal referrals to Agnesian HealthCare."

107. Since 1996, the DA has been adjusted several times to perpetuate its improper purpose – *i.e.*, to ensure that high referring specialties are paid more to ensure their continued referrals. Specifically, the Agnesian Board has on several occasions raised the DA to accommodate the demands of physicians who refer substantially to Agnesian physicians and facilities.

108. For example, in 2009, the Clinic's primary care physicians asked the Clinic Board to increase their DA. At the time, there was no evidence that their compensation was low compared to regional or national benchmarks. In fact, an analysis of their compensation for the prior year conducted by the Medical Group Management Association found that the pay for the Clinic's family practice and internal medicine physicians was between the 80th to 90th percentile of pay for all such physicians, even though their productivity was between the 49th and 64th percentile compared to the benchmarks. The Pediatricians' pay was in the 67th percentile, even

though their productivity was only in the 37th percentile. Nonetheless, the DA for each of the primary care specialties was increased by 6%.

109. Originally, the Clinic Board proposed to pay for this increase by reducing the DA for all non-primary care specialties (the "Specialists") by 2%. The Specialists objected strenuously to this proposal. Instead, then, the Clinic Board proposed to fund the increase for the primary care physicians by reducing the DA of only a limited number of specialties (Interventional Cardiology, Dermatology, Gastroenterology, Oncology and Otolaryngology) by 6%. These five targeted specialties again objected.

110. During these discussions, one prominent specialist encouraged the other Specialists to accept the cut rather than run the risk of losing the referrals from the primary care physicians. He explained to the other Specialists that he had previously had a dispute with one of the Clinic's pediatricians. During the course of the dispute, the pediatrician stopped referring patients to him. He recounted this experience to encourage the specialists to appreciate the risk they faced if they did not keep the primary care physicians happy by increasing their pay.

111. Ultimately, the five targeted specialties agreed to accept a 4% reduction in their DA. Agnesian agreed to cover the remaining cost of the salary increase for the primary care physicians, to keep the physicians in the five targeted specialties (which generally perform high-paying procedures at the hospital) happy and to appease the primary care physicians.

112. Agnesian's payment of this additional compensation is a kickback to the primary care doctors to induce them to continue referring to Agnesian facilities and the FDLRC physicians who perform procedures at Agnesian. It is also a kickback to the Clinic specialists to induce them to continue referring to, and performing procedures at, Agnesian facilities.

113. Similarly, in April 2008, the Clinic Compensation Committee discussed a proposal to increase the DA of any physician who stopped performing surgery (and thus, presumably, referred that surgery to another Clinic physician). The proposal was not adopted but an alternate proposal setting the DA of any physician who stopped performing surgeries at 1.256 was adopted. This alternate approach had the same practical effect because a DA of 1.256 is higher than the DA for the specialists who typically perform surgical procedures (*e.g.*, orthopedists whose DA is 1.0817; general surgeons whose DA is 1.1155; interventional cardiologists whose DA was 1.25 in 2008).

114. In another case, around 2004, the FDLRC interventional cardiologists – a specialty that typically performs lucrative procedures at the hospital – demanded the Agnesian Board increase their DA and threatened to leave if it was not raised. The Board agreed to increase their DA by 6.7%.

115. A few years earlier, a high-referring FDLRC gastroenterologist demanded the Agnesian Board raise his DA by threatening to leave if his demands were not met. Again, the Board consented. The DA for gastroenterology was raised by more than 25%, from 1.0743 to 1.351.

116. There is widespread awareness among the FDLRC physicians that the DA is intended to reward physicians for their internal referrals. For example, in November 2008, the Clinic's two physiatrists unsuccessfully requested an adjustment to their compensation methodology. In arguing for an increase in their DA, they pointed out, "[w]e could argue that our DA is erroneously low as we do order significant patient evaluation testing (MRI's, CT's, x-ray, etc) and referrals to the procedurists at the surgery center."

117. In 2013, the physiatrists again approached the Committee about an increase in their DA. They again argued that their tests "serve[] as an entry point test for services" and thus they should have a DA in line with that of other departments "working in the same practice base." In other words, because their work leads to significant referrals, their DA should be adjusted to match that of other high-referring specialties (such as family medicine physicians and internists). This time the Committee agreed to guarantee the physicians' 2013 income through 2014 and then revisit the DA issue if the physicians agreed to stay for 2 years.

118. Specialists that send fewer referrals to their fellow FDLRC physicians and perform few procedures at the hospital have had little luck convincing the Clinic Board to adjust their DAs upwards. For example, around 2010, the Clinic's rheumatologist, Dr. Owens, requested that her DA be increased. Despite the fact that as of 2008 she was one of only two FDLRC physicians paid below the national benchmark median for compensation per wRVU for her specialty, the Clinic refused to increase her DA.

B. Agnesian Improperly Compensates FDLRC Physicians by Giving Them a Portion of the Fees Earned by Agnesian Facilities for Services Provided by those Facilities

119. According to the PSA governing FDLRC and AHC's relationship, each physician's "net monthly production" should equal the amount Agnesian collects from the patients and/or insurers for services personally performed by the physician. .

120. However, based on his analysis of discrepancies between physician compensation, physician productivity, and reported collections data for various specialties including, *inter alia*, oncology, Relator believes, and on that basis alleges, that Agnesian includes, for at least some specialties, services not personally performed by the physician at issue in the "net monthly production" value when calculating the physician's base compensation.

Specifically, Relator believes that, in practice, for certain high-referring specialties (*e.g.*, oncology) Agnesian credits physicians with collections for services they don't perform such as technical fees, facility fees, drugs, or other referrals

121. Agnesian's payments to its oncologists are particularly suspect. In Relator's experience, there is consistently a substantially larger discrepancy between their income and productivity than for other FDLRC physicians. Their compensation is routinely above the 80th percentile when compared to regional and national benchmarks, while their productivity is below the 40th percentile. Such a discrepancy is difficult to imagine if their compensation is truly tied to the collections for the work they do. Given this significant discrepancy it is likely that they are receiving credit for the lucrative chemotherapy drugs billed by the hospital.

122. Moreover, Agnesian goes out of its way to obscure, or outright hide, even basic information about how it calculates the "collections" amount attributable to each physician for purposes of calculating his or her base salary. For example, Relator has repeatedly asked Agnesian for the claims billing and payment detail used to calculate his "collections" amounts. Agnesian has never given him that data. Similarly, Relator has heard numerous other physicians complain that Agnesian will not share such basic information with them.

123. In response to questions about general policies and procedures for calculating collections, Agnesian provides limited, vague and/or contradictory information. For instance, many services and procedures, such as x-rays, are billed to Medicare and other providers "globally" – meaning Agnesian submits one bill that covers both the "professional" component (the physician fee) and a "technical" component (meant to cover the clinic or hospital's overhead). Relator has been told by Kate Cole, the Clinic's Accountant, that Agnesian cannot easily split payments made for such globally-billed services into professional and technical

components, and thus must use a complicated algorithm to allocate to the physicians the professional component

124. However, there are well established procedures (*e.g.*, the CPT-based relative value unit ("RVU") methodology) recognized by Medicare and elsewhere in the health care industry to establish the relative cost of the professional and technical components if billed separately. Moreover, to the extent that Relator has been allowed to see certain tables showing parts of how Agnesian's methodology works, it appears Agnesian's methodology routinely assigns more of the overall fee to the professional component (and thus to the physician) than the industry-recognized, CPT-based relative value unit methodology would. As such, the physicians are given more of the overall fee than they would receive if the professional component and the technical component were billed separately or allocated using the industry-recognized CPT/RVU. Functionally, this means that Agnesian is giving these physicians a share of its billings for services performed by the Clinic or hospital, not the physician.

125. The use of a complex and opaque methodology when a simple one is readily available, as well as the consistent discrepancy between FDLRC physician compensation and productivity, indicates that Agnesian is likely adjusting collections to reward valuable physicians, such as those who refer heavily and/or perform lucrative procedures at hospital facilities.

126. For these reasons, Relator alleges on information and belief, that Agnesian is regularly giving physicians a portion of the technical component fees received in payment for services performed by the Clinic and/or hospitals.

C. Agnesian Provides Additional Improper Compensation to FDLRC's Physicians Through Its Deferred Compensation Plan

127. Another way that Agnesian overcompensates the Clinic physicians is through its deferred compensation plan (the "DCP"). The DCP compensation is problematic both because it further inflates the already-too-high compensation Agnesian pays these physicians, and because this compensation is explicitly tied to an agreement by the physicians not to compete with Agnesian. As such, this is effectively a payment by Agnesian to these physicians to ensure that they continue to refer their patients to Agnesian.

128. FDLRC physicians, upon becoming "shareholders" of the Clinic are enrolled in the DCP. Upon enrollment, the physician is given a deposit into their account equal to 4.5% of the value of all compensation the physician received as an associate. Thereafter, each physician's account is credited annually with an amount equal to 7.5% of his or her cash compensation.

129. The physician's entitlement to these funds vests over the course of ten years, with half vesting after five years and an additional 10% vesting per year thereafter.

130. Regardless of whether the funds are vested, however, the physician's right to receive the funds is explicitly tied to the physician's agreement to avoid "competing" with Agnesian for two years after the physician leaves FDLRC.

131. Prior to 2009, the non-compete extended over about 30 miles. It was amended and expanded in 2009 when the plan administrator changed. This change coincided with increased compensation for physicians under the DCP as the physicians became responsible for significantly lower management fees.

132. Under the current DCP, competition is defined as "engaging in the practice of medicine in competition with Agnesian Healthcare, Inc. or any affiliate either (i) within the Wisconsin counties of Winnebago, Calumet, Sheboygan, Washington, Dodge, Fond du Lac, Green lake, Manitowac or Outagamie or (ii) as a direct or indirect employee or contractor with . . . Aurora Medical Group, including any of its affiliates and/or successors." The geographic limitation imposed by the excluded counties would essentially require a physician to practice at least sixty miles away from Fond du Lac.

133. Thus, through the DCP, Agnesian pays these physicians a bonus that is directly tied to the volume and value of services the physician previously performed for and referred to AHC, and makes this payment explicitly contingent on the physician (so long as he or she wishes to continue to live and work in the area): 1) remaining affiliated with Agnesian; 2) refraining from offering medical services in Agnesian's market to patients that would otherwise likely seek services from Agnesian; and 3) refraining from affiliating with a competitor and, correspondingly, sending such a competitor their referrals.

134. CMS has noted that payments to physicians for non-compete agreements by providers in a position to retain their referrals are inherently suspect under the Anti-Kickback statute because of the risk that such payments are merely disguised payments for referrals. *See* Letter from D. McCarty Thorton, Associate General Counsel, Department of Health and Human Services, Inspector General Division, to T.J. Sullivan, Technical Assistant (Health Care Industries), Office of the Associate Chief Counsel, Internal Revenue Services, December 22, 1992, http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm ("Specific items that we believe would raise a question as to whether a payment was being made for the

value of a referral stream would include, among other things: . . . payment for covenants not to compete").

135. That risk is particularly high in this case because the FDLRC physicians already enter into a more modest non-compete agreement as part of their standard employment agreement. This non-compete prohibits each physician, for two years from the end of his/her employment with the Clinic, from practicing the medical specialty he/she practiced for the Clinic within 10 miles of any location at which the physician regularly worked during the two years prior to his/her termination.

136. Pursuant to the Anti-Kickback Statute and Stark Law, non-competition agreements may be appropriate to protect an employer's legitimate interests, *e.g.*, confidential business information. However, they must be limited in scope so as to protect only such legitimate interests. Non-competes may not be used as a pretext to pay physicians to ensure the flow of their referrals to a hospital or related entity. *Cf. United States ex rel. Singh v. Bradford Regional Medical Center*, 752 F. Supp. 2d 602, 622-23 (W. D. Pa. 2010) (finding that a report calculating the value of a non-compete based on the referrals that would flow to the provider in the presence of the non-compete demonstrated that the payments for the non-compete "took into account" the volume and value of the physicians' referrals in violation of the Stark Law).

137. The restrictions of the DCP non-compete, which would require a physician in Fond du Lac to travel at least 60 miles in any direction to avoid the non-compete, go far beyond keeping a physician from soliciting clients with whom he/she formed relationships as a result of Agnesian's efforts. Rather, the non-compete effectively prevents physicians from drawing referrals from Agnesian facilities, either by independently offering professional services or working for Agnesian's primary competitor.

D. Agnesian Enters Into Special Compensation Arrangements with High Referring Physicians

138. Beyond the standard compensation arrangements described above, Agnesian makes special deals to pay extra compensation to physicians who make substantial referrals to, or perform lucrative procedures at, Agnesian.

139. For example, at least between 2008 and 2011, Agnesian paid Dr. Dennis Woodhall $200,000 per year to serve as the medical director for Agnesian's cardiology program. Relator understands that Dr. Woodhall did little to no work to justify this compensation. Rather, this money was included in Dr. Woodhall's compensation to get his overall compensation to the desired level. He was the first cardiothoracic surgeon at Agnesian and established the Heart Surgery program, a very profitable program that generates millions of dollars in facility fees for services including, *inter alia*, catheterizations and heart surgeries.

140. In 2012, the Agnesian billing office disclosed to the Clinic Board that the Clinic's ENTs had been receiving credit when calculating their "collections" for audiograms that were incorrectly credited to them. This had resulted in approximately $10,000/year in additional compensation for each ENT. Relator believes that this improper crediting process was halted but the improper compensation was never disclosed to government payers or recouped. Far from taking steps to correct the improper compensation, the Clinic Board's sole interest was in determining a means of ensuring that the compensation of these specialists was not decreased as a result of the corrected billing.

141. The Clinic's primary care physicians have also received special treatment from Agnesian. In addition to the DA adjustment described above, the Clinic's primary care doctors have been granted certain allowances not given to other doctors. For example, the primary care doctors are allowed to cap the number of Medicare and Medicaid patients they see. This

effectively increases the compensation of the primary care physicians because their cash compensation is based on their collections and commercial payers generally pay more than Medicare and Medicaid.

142. Agnesian was forced to open another clinic location wholly staffed by nurse practitioners and physician assistants to see the Medicare and Medicaid patients who could not get in to see the Clinic's primary care doctors. To free the primary care doctors from supervisory responsibilities at these locations, Agnesian also brought in hospital-employed doctors to perform these duties.

143. In addition, the primary care physicians have been permitted to retain their high DAs despite refusal to take call at St. Agnes. Under the standard Clinic employment contract, taking call is a requirement for Clinic physicians to retain their right to full-time compensation. Despite this, the primary care physicians, per their demand, have been given the option to retain their full-time compensation despite their refusal to take standard call, by providing other more lifestyle-friendly services such as extending office hours, providing limited call coverage (predominantly by telephone), and visiting nursing home patients.

E. The Combined Effect of These Practices Is That Agnesian Substantially Overpays FDLRC Physicians To Secure Their Referrals in Violation of the Stark Law and the Anti-Kickback Statute

144. The PSA governing the relationship between AHC and FDLRC requires AHC to conduct an annual review of the compensation paid to FDLRC physicians to ensure that the compensation is "reasonable and that such does not . . . exceed fair market value for services in arms length transactions." In addition, FDLRC must certify that the compensation provided by AHC to FDLRC and by FDLRC to each individual employee is

"reasonable, based upon (i) the most recent annual Physician Compensation Survey published by Medical Group Management Association ["MGMA"]; (ii) available data from the American Medical Group Practice Association; (iii) available data from state and/or local medical societies, which may help to establish the ranges of salaries for like specialties in Wisconsin and in communities similar in size and socio-economic demographics; and (iv) other relevant information, including the current [salary and benefits payments to FDLRC] and each individual Physician relative to the collective and individual performance as reflected in the Productivity Indicators for each individual Physician."

145. To meet this requirement, in May 2008, Agnesian hired MGMA's Health Care Consulting Group to "assess the productivity and compensation levels" of its employed physicians.

146. MGMA issued a "draft" report that found substantial problems with Agnesian's physician compensation practices. Specifically the report found that Agnesian's compensation plan did *not* follow "generally accepted criteria for better performing practices" because, *inter alia*,:

- "Compensation isn't correlated to employment market surveys."
- "Almost every specialty department's compensation exceeds market survey medians."
- "Production . . . generally does not correlate with the higher physician compensation."

- "In almost every case, the value of a work RVU [*i.e.*, the amount paid per unit of work] for the Group exceeds survey benchmarks." and
- "Compensation has an indirect correlation to physician productivity."

147. MGMA's report included tables of data showing that the amount Agnesian paid its physicians per wRVU exceeded benchmark market rates for all but two physicians. The physician per wRVU payments exceeded the benchmark medians by up to 220%. Eleven specialties (of the 22 reviewed) had disparities between their compensation and production percentiles of 20 points or more.

148. The draft MGMA analysis was never turned into a final report, and Agnesian did not engage MGMA's services further to fix these problems.

149. Instead, Agnesian reverted to use of its own internal review process, whereby the Clinic's Administrator (until recently, Dennis Yunk) performed a rough analysis of physician compensation. Mr. Yunk had no training or experience in assessing physician compensation. He determined that most physicians' compensation was appropriate simply because it fell within one standard deviation of the mean compensation for that specialty – regardless of physician productivity, hours worked, or any other factor.

150. For the remaining physicians, Mr. Yunk's 2008 analysis ignores most MGMA standards generally consulted in assessing physician pay (such as productivity, collections, or pay per wRVU) and instead relies almost entirely on a single cherry-picked measure ("gross charges") to justify the pay of highly-compensated physicians. As gross charges generally bear no relation to costs or effort, and are often arbitrarily set by hospitals (particularly when relatively unconstrained by competition and a lack of pricing transparency), this measure, standing alone, has little value in assessing a physician's fair market value compensation.

151. Mr. Yunk continued to conduct the Clinic's annual analysis of physician compensation through his departure in January 2014. He has confirmed to Relator that his analyses consistently relied on "gross charges" to justify the compensation of highly-paid physicians. He explained his reliance on this measure by saying something to the effect of: "the high earners bill a lot so they should make a lot."

152. Throughout his time at Agnesian, the analyses of FDLRC physician compensation that Relator has seen have shown a consistent pattern, where physician compensation far exceeds benchmark levels given the physicians' productivity.

153. This overcompensation is driven by the improper compensation methodologies described above as well as by Agnesian's over-valuation of physician services. For example, Agnesian credits FDLRC physicians with 30% of billed charges for charity care and bad debt patients. This equates to "collections" (for purposes of calculating physician compensation), equal to about 2 to 3 times what Medicare would pay for the service, by definition what it would cost a reasonably efficient practice to provide the service.

154. These overpayments have been and continue to be made knowingly. At a recent meeting of the PSA Committee, Agnesian's Medical Director, Dr. Derek Colmenares, stated that Agnesian had considered further external evaluations of physician compensation in the past, "but never did it because we were afraid it would show that we have a problem."

155. Agnesian uses its overly generous base compensation practices to lure physicians to Agnesian and away from Aurora. For example, around 2010, two independent orthopedic surgeons in Fond du Lac were contemplating affiliating with a local hospital. They leased office space in a building owned by Aurora, sent all of their lab work and ancillaries to Aurora facilities in Fond du Lac, and performed their surgeries at the Aurora surgery center in Fond du Lac. To

convince these doctors to join FDLRC, Agnesian personnel offered them an income guarantee but assured them that no guarantee was necessary because the physicians would make $100,000-$150,000 more per year based solely on FDLRC's base compensation methodology. The physicians joined FDLRC and have since sent virtually all of their referrals to Agnesian's facilities.

156. Agnesian's above fair market value, commercially unreasonable, and referral-based compensation constitutes payment in exchange for referrals as defined by the Anti-Kickback Statute and creates improper financial relationships between AHC and FDLRC and the physicians employed by the Clinic as defined by the Stark Law. These relationships do not fall within a safe harbor for either statute.

157. All of Agnesian's physicians treat Medicare and Medicaid patients. Agnesian bills Medicare and Medicaid for services provided by these physicians. In 2012, on average, Medicare made up 36% of FDLRC's patient base and Medicaid constituted another 9%.

158. All claims for services referred by these physicians are false under the False Claims Act by virtue of the improper compensation arrangements and kickbacks between the physicians and the network.

Count I
False Claims Act
31 U.S.C. §§3729(a)(1)(A)-(B) and (G)

159. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 158 above as though fully set forth herein.

160. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

161. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

162. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims.

163. By virtue of the acts described above, Defendants conspired to submit false claims, cause false claims to be submitted, and make and/or us false or fraudulent records material to false claims.

164. By virtue of the acts described above, Defendants knowingly concealed overpayments from the United States Government and failed to remit such overpayments.

165. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

166. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

167. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

Count II
Wisconsin False Claims for Medical Assistance Law
Wis. Stat. §§ 29.931(2)(a)-(c), (g)

168. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 158 above as though fully set forth herein.

169. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Law.

170. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false claims to the Wisconsin State Government for payment or approval.

171. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

172. By virtue of the acts described above, Defendants conspired to defraud the Wisconsin State Government by obtaining payment of false claims for medical assistance.

173. By virtue of the acts described above, Defendants knowingly and improperly made or used a false statement to avoid an obligation to pay or transmit money or property to the Wisconsin State Government.

174. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

175. By reason of Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

176. Additionally, the Wisconsin State Government is entitled to civil penalties of at least $5,000 for each and every violation alleged herein.

PRAYER

WHEREFORE, Dr. Searle prays for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq*. and Wis. Stat. § 29.931.

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of at least $5,000 for each violation of Wis. Stat. § 29.931;

4. That Plaintiff-Relator Dr. Searle be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act and the comparable provisions of the Wisconsin False Claims Act;

5. That Plaintiff-Relator Dr. Searle be awarded all costs of this action, including attorneys' fees and expenses; and

6. That Plaintiff-Relator Dr. Searle recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Dr. Searle hereby demands a trial by jury.

Dated: August 8, 2014

By: s/ Nola J. Hitchcock Cross

Nola Hitchcock Cross
njhcross@crosslawfirm.com
CROSS LAW FIRM, S.C.
845 North 11th St.
Lawyers' Building
Milwaukee, Wisconsin 53233
Tel: (414) 224-0000
Fax: (414) 273-7055

Timothy P. McCormack
tmccormack@phillipsandcohen.com
Peter W. Chatfield
peter@phillipsandcohen.com
Molly B. Knobler
mknobler@phillipsandcohen.com
PHILLIPS & COHEN LLP
2000 Massachusetts Ave, NW
Washington, DC 20002
Tel: (202) 833-4567
Fax: (202) 833-1815

Attorneys for Plaintiff-Relator
Dr. Clark Searle